

CLAIMS

What is claimed is:

1. A medicinal aerosol solution formulation product with improved chemical stability, comprising:
 - an aerosol canister equipped with a metering valve, said metering valve including a rubber valve gasket;
 - said aerosol canister containing a medicinal aerosol solution formulation comprising an active ingredient subject to a degradation by means of peroxides and /or other leachables, a hydrofluorocarbon propellant, a co-solvent, and optionally a low-volatility component; and
 - said aerosol canister having a rim with rounded edges adapted to prevent contact of a sharp edge with said rubber gasket.
2. The product of claim 1, wherein the canister has a rolled neck.
3. The product of claim 1, wherein the canister has a rolled-in rim.
4. The product of claim 1, wherein the canister has a partly rollover rim.
5. The product of claim 1, wherein the canister has a full rollover rim.
6. The product of claim 1, wherein the valve is washed before crimping of the valve upon the canister with a pharmaceutically acceptable solvent.

7. The product of claim 1, wherein the valve is washed before crimping of the valve upon the canister with ethanol.

8. The product of claim 1, wherein the active ingredient is a corticosteroid.

9. The product of claim 8, wherein the corticosteroid is a 20-ketosteroid.

10. The product of claim 9, wherein the 20-ketosteroid is selected from the group consisting of budesonide and its epimers, mometasone furoate, triamcinolone acetonide, butixocort and ciclesonide.

11. The product according to claim 1, wherein the low-volatility component is selected from the group consisting of glycerol, propylene glycol, polyethylene glycol and isopropyl myristate.

12. The product according to claim 1, wherein the co-solvent is ethanol.

13. The product according to 1, wherein the propellant is selected from HFA 227, HFA 134a and their mixtures.

14. The product according to claim 1, wherein part or all of the internal surfaces of said canister consists of stainless steel, anodized aluminum or are lined with an inert organic coating.

15. The product according to claim 14, wherein the inert organic coating is perfluoroalkoxyalkane, perfluoroalkoxyalkylene, perfluoroalkylenes such as polytetrafluoroethylene, epoxy-phenol resin or fluorinated-ethylene-propylene, polyether sulfone, or their combinations.

16. The product according to claim 1, wherein part or all of the internal surfaces consist of anodized aluminum.

17. A process for making a chemically stable aerosol solution formulation product containing an active ingredient subject to a degradation by means of peroxides or other leachables, comprising the steps of:

forming a rim on a canister having rounded edges;

filling the canister with a pressurized aerosol solution formulation, said formulation comprising an active ingredient subject to a degradation by means of peroxides or other leachables,

providing the canister with a valve having a rubber gasket as a component thereof, wherein the rounded edges of the canister prevent contact of a sharp edge with the rubber used as a valve gasket.

18. The process according to claim 17, wherein the rim of the canister is selected from the group consisting of a rolled neck, a rolled-in rim, a part rollover rim and a full rollover rim.

19. A process according to claim 17, further comprising the step of washing the valve with ethanol before attaching the valve to the canister.

20. The process according to claim 17, wherein part or all of the internal surfaces of said canister consists of stainless steel, anodized aluminum or are lined with an inert organic coating.

21. A process for the stabilization of an aerosol solution formulation containing an active ingredient subject to a degradation by means of peroxides or other leachables contained in a pressurized metered dose inhaler, comprising the steps of providing a canister with a rim having rounded edges; and washing a valve for use in connection with said canister with ethanol prior to connecting said valve to said canister.

22. The process according to claim 21, wherein said canister has a rolled neck.

23. The process according to claim 21, wherein said canister has a neck selected from the group consisting of a rolled-in rim, a part rollover rim and a full rollover rim.